UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF PENNSYLVANIA
PITTSBURGH DIVISION

KELI CHASE MBAYE,

Plaintiffs, CASE NO:

vs.

BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER PHARMACEUTICALS CORPORATION, BAYER AG, BERLEX LABORATORIES, INC., BERLEX, INC., BAYER SCHERING PHARMA AG, JOHN DOE MANUFACTURERS A-Z, and JOHN DOE DISTRIBUTORS A-Z,

Defendants.

_____/

COME NOW KELI CHASE MBAYE, by and through the undersigned counsel, and for their Complaint hereby aver and state as follows:

NATURE OF THE ACTION

1. This is an action for strict product liability, fraud, civil conspiracy and commercial bribery, and punitive damages brought by Plaintiff for damages associated with the ingestion of the pharmaceutical drug YASMIN, an oral contraceptive developed, designed, licensed, manufactured, distributed, sold, and/or marketed by Defendants.

2. As a result of the ingestion of YASMIN, Plaintiff k has suffered injuries to her person including, but not limited to, a pulmonary embolism, pneumonia.

THE PARTIES

3. Plaintiff, KELI CHASE MBAYE, (herein "Plaintiff"), resides in Columbia, Maryland.

4. Defendant BAYER CORPORATION is, and at all times relevant was, a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Rd., Pittsburgh, Pennsylvania 15205.

5. At all times relevant, Defendant BAYER CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State ofMaryland, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YASMIN.

6. Defendant BAYER HEALTHCARE LLC, is, and at times relevant was, a limited liability corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 100 Bayer Road, Pittsburg, PA 15205.

7. At all times relevant, Defendant BAYER HEALTHCARE LLC was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Maryland, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YASMIN.

8. Defendant BAYER HEALTHCARE LLC is wholly owned by Defendant BAYER CORPORATION.

9. Defendant BAYER PHARMACEUTICALS CORPORATION is, and at times relevant was, a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 1400 Morgan Lane, West Haven, Connecticut.

10. At all times relevant, Defendant BAYER PHARMACEUTICALS CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of

Maryland, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YASMIN.

11. As of January 1, 2008, Defendant BAYER PHARMACEUTICALS CORPORATION was merged into Defendant BAYER HEALTHCARE PHARMACEUTICALS INC.

12. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC., is and at times relevant was, a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

13. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc., and is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

14. At all times relevant, Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Maryland, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YASMIN.

15. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. is the holder of approved New Drug Application ("NDA") for YASMIN.

16. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. are, and at all times relevant were, foreign corporations with their headquarters and principal places of business at Montville, New Jersey and with a post office address of P.O. Box 1000, Montville, New Jersey, 07045 and places of business located at 6 West Belt Road, Wayne, New Jersey 07470.

17. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were integrated into Bayer HealthCare AG and operates as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

18. At all times relevant, Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Maryland, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YASMIN.

19. Defendant BAYER SCHERING PHARMA AG, formerly known as Schering AG, is a pharmaceutical company that is organized and existing under the laws of the Federal Republic of German, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

20. Defendant BAYER SCHERING PHARMA AG is a corporate successor to Schering AG.

21. Schering AG was renamed BAYER SCHERING PHARMA AG effective December 29, 2006.

22. Defendant BAYER SCHERING PHARMA AG'S headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205.

23. At all times relevant, Defendant BAYER SCHERING PHARMA AG was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Maryland, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YASMIN.

24. Defendant BAYER SCHERING PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive, YASMIN.

25. Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

26. Defendant BAYER AG is the third largest pharmaceutical company in the world.

27. Defendant BAYER AG is the parent/holding company of all other named Defendants.

28. Defendant BAYER AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205.

29. At all times relevant, Defendant BAYER AG was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Maryland, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YASMIN.

30. At all times relevant, Defendant BAYER AG was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YASMIN.

31. Defendants John Doe Manufacturers A-Z (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto were in the business of developing, researching, selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling, marketing, and/or placing, either directly or indirectly through third parties or related entities, pharmaceutical drugs including YASMIN into interstate commerce, and derived substantial revenue from these activities.

32. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc. and Berlex,

Inc., Bayer Schering Pharma AG, Bayer AG, John Doe Manufacturers and Distributors A-Z shall be referred to herein individually by name or jointly as "Defendants."

33. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

34. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

JURISDICTION AND VENUE

35. This Court has jurisdiction over this action pursuant to 28 U.S.C.A. § 1332, as there is complete diversity of citizenship between Plaintiff and Defendants, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

36. This Court has jurisdiction over this action pursuant to 28 U.S.C.A. § 1332, as there is complete diversity of citizenship between Plaintiff and Defendants, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

37. Venue is proper in the Western District of Pennsylvania pursuant to 28 U.S.C.A. § 1391, as a substantial part of the events and/or omissions giving rise to these claims occurred within this district, as this district is the principal place of business for multiple Defendants named in this Complaint.

38. The Court has personal jurisdiction over Defendants consistent with the Pennsylvania and United States Constitution because multiple Defendants maintain their principal place of business in Pittsburgh, Pennsylvania and caused tortious injury to Plaintiff due to an act

or omission that occurred by virtue of Defendants' regularly conducted business there, from which they respectively derive substantial revenue.

FACTS

39. Yasmin, (a predecessor to YAZ), known generically as drospirenone and ethinyl estradiol, is a combination birth control pill originally developed by Defendant BERLEX LABORATORIES, INC. and/or Defendant BERLEX, INC containing the hormones estrogen and progestin.

40. The estrogen is ethinyl estradiol and the progestin is drospirenone, (3 mg of drospirenone and 0.03 mg of ethinyl estradiol per tablet).

41. Combination birth control pills are referred to as combined hormonal oral contraceptives.

42. Yasmin was approved by the FDA in April, 2001.

43. In 2006, Bayer acquired Defendant BERLEX LABORATORIES, INC. and/or Defendant BERLEX, INC, and began marketing an almost identical drug, YAZ (which contains 3 mg of drospirenone and 0.02 mg of ethinyl estradiol per tablet).

44. The difference between Yasmin and other birth control pills on the market is that drospirenone has never before been marketed in the United States and is unlike other progestins available in the United States.

45. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

46. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands

Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin was suspected as the cause, including two deaths.

47. Defendants have been warned at least three times by the FDA; in 2003, 2008 and 2009, for misleading the public through the use of ads which overstate the efficacy of YAZ and/or its predecessor Yasmin, and minimize serious risks associated with the drug.

48. The use of YASMIN has a prothrombotic effect resulting in thrombosis such as the pulmonary embolism suffered by Plaintiff.

49. Defendants ignored the correlation between the use of YASMIN and increased thrombosis formation despite the wealth of scientific information available.

50. Upon information and belief, Defendants knew or should have known about the correlation between the use of YASMIN and a prothrombotic effect and still promoted, sold, advertised, and marketed the use of YASMIN.

51. Defendants falsely and fraudulently represented to the medical and healthcare community, to Plaintiff, the FDA, and the public in general, that YASMIN had been tested and was found to be safe and/or effective for its indicated use.

52. These false representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense and/or purchase YASMIN for use as a contraceptive, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff.

53. Defendants knew and were aware or should have been aware that YASMIN had not been sufficiently tested, was defective in its design and testing, and/or that it lacked adequate and/or sufficient warnings.

54. Defendants knew or should have known that YASMIN had a potential to, could, and would cause severe and grievous injury and death to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

55. In representations to Plaintiff, her healthcare providers, and/or the FDA, Defendants also fraudulently concealed and intentionally omitted the following material information:

A. That YASMIN is not as safe as other available contraceptives;

B. That the risks of adverse events with YASMIN (drospirenone and ethinyl estradiol) was higher than those of other available contraceptives;

C. That the risks of adverse events with YASMIN was not adequately tested and/or known by Defendants;

D. Plaintiff was put at risk of experiencing serious and dangerous side effects including, but not limited to, a pulmonary embolism, as well as other severe and personal injuries, physical pain, and mental anguish;

E. That patients needed to be monitored more regularly than normal while using YASMIN; and

F. That YASMIN was designed, tested, manufactured, marketed, produced, distributed and advertised negligently, defectively, fraudulently and improperly.

56. Defendants were under a duty to disclose to Plaintiff and her physicians, hospitals, healthcare providers and/or the FDA the defective nature of YASMIN.

57. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to person who used YASMIN, including Plaintiff.

58. Defendants made the misrepresentations and/or actively concealed information concerning the safety and efficacy of YASMIN with the intention and specific desire that

the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, would rely on such in selecting YASMIN as a contraceptive.

59. Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of YASMIN in their labeling, advertising, product inserts, promotional material or other marketing efforts.

60. The misrepresentations of and/or active concealment by Defendants were perpetuated directly and/or indirectly by Defendants, its sales representative, employees, distributors, agents and/or detail persons.

61. Defendants knew that Plaintiff, her healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding YASMIN, as set forth herein.

62. The misrepresentations of and/or active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continue to misrepresent the potential risks and serious side effects associated with the use of YASMIN.

63. Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, about the potential risks and serious side effects associated with the use of YASMIN in a timely manner, yet they failed to provide such warning.

FACTS REGARDING PLAINTIFF

64. Plaintiff was first prescribed YASMIN by her health care provider in approximately January, 2007.

65. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest YASMIN to her detriment.

66. As a result of using Defendants' product YASMIN, Plaintiff suffered serious and life-threatening side effects including but not limited to, a pulmonary embolism, pneumonia, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.

67. Plaintiff did not discover, nor did she have any reason to discover that her injury was a result of a defective drug and/or the wrongful conduct of Defendants, as set forth herein, until at least June, 2009.

CAUSES OF ACTION

COUNT I - STATUTORY PRODUCTS LIABILITY

68. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

69. Defendants are manufacturers, and distributors, which designed, produced, created, made, constructed and/or assembled the drug, YASMIN.

70. YASMIN reached the ultimate users without substantial change in the condition it was sold.

71. YASMIN reached the ultimate users without substantial change in the condition it was sold.

72. Said defect was a result of Defendants' failures including, but not limited to:

A. Defendants' failure to include adequate warnings that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and serious side effects of the drug;

B. Defendants' failure to adequately and properly test and inspect the drug before placing the drug on the market;

C. Defendants' failure to conduct sufficient testing and inspection of the drug which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to, a pulmonary embolism, and other serious and life threatening side effects;

D. Defendants' failure to adequately warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff of the potential risks and other serious side effects associated with the drug, including, among other things, a pulmonary embolism and other serious and life threatening side effects;

E. Defendants' failure to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risks associated with the use of the drug;

F. Defendants' failure to recall and/or remove the drug from the stream of commerce despite the fact that Defendants knew or should have known of the defective and unreasonably dangerous nature of the drug, including the significant health risks associated with the use of the drug; and

G. Defendants' encouragement of misuse and overuse while failing to disclose the side effects of the drug to the medical, pharmaceutical and/or scientific communities, and users and/or consumers, including Plaintiff, in order to maximize profit from sales.

74. Plaintiff was using YASMIN in the manner for which it was intended and/or in a reasonably foreseeable manner.

75. Plaintiff was not aware of and reasonably could not have discovered the dangerous nature of YASMIN.

76. As a result of the foregoing acts and omissions, Plaintiff suffered serious and life-threatening side effects including but not limited to, a pulmonary embolism, pneumonia, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.

COUNT II - FRAUD

77. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

78. Defendants having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of YASMIN described herein, owed a duty not to deceive the public regarding its drug's safety and to provide accurate and complete information regarding the product.

79. Since the drug's approval and on multiple occasions to the present date, Defendants fraudulently misrepresented information in various forms of media (including, but not limited to, ad campaigns, television, internet, etc.) regarding their product's safety.

80. At the time of Defendants' fraudulent misrepresentations, Plaintiff was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

81. Defendants breached their duties to Plaintiff by providing false, incomplete and misleading information regarding their product.

82. Defendants acted with deliberate intent to deceive and mislead Plaintiff, her medical providers, and the public.

83. Plaintiff reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

84. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff suffered serious and life-threatening side effects including but not limited to, a pulmonary embolism, pneumonia, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.

COUNT III - CIVIL CONSPIRACY AND COMMERCIAL BRIBERY

85. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

86. Defendants committed civil conspiracy, commercial bribery and conspiracy to commit commercial bribery in that fiduciaries of Defendants knowingly and/or intentionally offered, conferred, or agreed to confer benefits, gifts, and/or gratuities or conspired to do the same upon physicians, pharmacists, and insurance companies for the purpose of enticing these entities to use the drug YASMIN, and to convince their patients and others of the safety and effectiveness of YASMIN.

COUNT IV - PUNITIVE DAMAGES

89. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

90. Defendants engaged in fraudulent and malicious conduct towards the Plaintiff, her medical providers and the public, and thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff and the public.

PRAYER FOR RELIEF WHEREFORE, Plaintiff(s) pray(s) for judgment against the Defendants, jointly and severally, as follows:

A. For an award of compensatory damages, including damages against Defendants and each of them for medical and hospital expenses, loss of income, loss of consortium, and other damages according to proof at trial in excess of $75,000;

B. For an award of punitive or exemplary damages against Defendants and each of them in excess of $75,000;

C. For reasonable attorneys' fees and costs;

D. For pre-judgment interest; and

E. For such further and other relief the court deems just, equitable, and proper.

Dated: December 16, 2009

Respectfully Submitted,

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